EXHIBIT D

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	
	)	
v.	)	**Criminal No. 05-10282-RCL**
	)	
	)	
SERONO LABORATORIES, INC.,	)	
	)	
Defendant.	)	

GOVERNMENT'S SENTENCING MEMORANDUM

Now comes the United States of America, by and through its undersigned attorneys and files this memorandum which sets forth the Government's statement of the offense conduct in the above-captioned case, as well as the Government's recommendation regarding sentencing in accordance with the parties' global criminal and civil settlement agreement to resolve the criminal and civil liability of defendant Serono Laboratories, Inc., ("Serono Labs") and its related entities regarding the marketing and sale of the drug Serostim[1].

I. INTRODUCTION:

This memorandum describes the criminal conduct engaged in by Serono Labs and its employees, and thereafter sets forth the reasons supporting the global resolution of the criminal and civil charges in this case. This memorandum analyzes the estimated loss that Serono Labs and its co-conspirators caused Medicaid, other federal payors, and others. In addition to the

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[1] The purpose of this Memorandum is not to submit any new materials that have not already provided to the Court in the Presentence Report, but rather to streamline the statement of facts required to be made by the Government during the Rule 11 hearing set to take place on December 15, 2005, which will be followed immediately by sentencing.

criminal conduct, Serono Labs and its related Serono entities engaged in other conduct for which there may be insufficient evidence to establish criminal culpability but for which they have civil liability under the federal civil False Claims Act, 31 U.S.C. § 1329 *et seq*. and other civil statutes. The conduct for which the Serono entities have civil liability includes expanding the market for Serostim by promoting the drug for unapproved uses such as lipodystrophy; providing other forms of inducements to physicians to prescribe Serostim, such as giving BIA machines as part of a study protocol; paying excessive reimbursements for physician participation in SeronAIDS and SALSA, two studies run by Serono Labs; and entering into contracts with specialty pharmacies providing excessive remuneration for data collection and preferred provider status. In evaluating the losses caused by the criminal conspiracies to which Serono Labs is pleading guilty, the United States Attorney's Office was cognizant of and examined the related civil liability to insure that the global criminal and civil settlement fully and fairly punishes Serono Labs for its criminal conduct, and fully and fairly compensates the affected federal and state health care programs for all of the Serono entities' conduct.

II. THE PROPOSED CRIMINAL AND CIVIL RESOLUTION

The proposed criminal and civil resolution in this matter is the product of a more than four-year investigation and more than a year of negotiations between the United States Attorney's Office in this District and the Serono entities. The agreement includes: the plea agreement in this case setting forth Serono Labs's punishment for its criminal conduct; a side letter outlining the responsibilities of the remaining Serono corporate entities; a civil settlement agreement between the Serono entities and the United States resolving their civil liability to the Medicare, Medicaid and other federal programs; a Corporate Integrity Agreement with the

Office of Inspector General, Department of Health and Human Services, governing the remaining Serono corporate entities' future conduct as a provider of pharmaceutical products to beneficiaries of the various federal and state health care programs; and an agreement in principle, already signed by some states, concerning the Serono entities' financial responsibilities to the state Medicaid programs.

This settlement provides complete restitution for the federal programs which were the target of Serono Labs's conspiracies to violate the law. That restitution is contained in the civil settlement amount, and under that agreement, will be returned directly to the impacted programs. Because full restitution is being returned directly to the federal programs through the civil settlement payments, the parties agree that a restitution order is not necessary in this criminal action. Although the proposed settlement does not include restitution for private insurance companies who may have also suffered losses, to attempt to include these damages in this resolution would unduly complicate and prolong this sentencing proceeding. As in the recent TAP Pharmaceutical Products, Inc. global resolution, which involved a similar type of conspiracy to violate the law focused on federal program payors, it would be neigh-on impossible to determine the private side losses in this case. See, United States v. TAP Pharmaceutical Products, Inc., Crim. No. 01-CR-10354-WGY. As explained more fully below, to attempt to remedy losses by private entities would unduly complicate and prolong the sentencing proceeding in this case.

In summary, the agreements between the United States and the Serono entities include the following:

(A) Serono Labs agreed to plead guilty to two counts of conspiracy, one to

violate provisions of the Food Drug and Cosmetic Act ("FDCA"), and one to violate the Anti-Kickback Act, and to pay a **$136,936,000 criminal fine**. The plea agreement between Serono Labs and the United States specifically states that Serono Lab's conduct caused losses of $104,914,000 to Medicaid and others in connection with the first count involving the introduction of adulterated BIA devices into interstate commerce, and losses of $9,200,000 to Medicaid in connection with the second count involving the offer and payment of a kickback to physicians consisting of free trips to Cannes, France.

(B) Serono Labs and its related entities agreed to settle their federal civil False Claims Act liabilities and to pay the United States government **$305,077,000 plus interest in federal civil damages**[2] for losses suffered by the federal Medicaid and other federal health care programs as a result of the Serono entities' sales and marketing misconduct involving Serostim.

(C) The Serono entities agreed to settles their civil liabilities to the fifty states and the District of Columbia in an amount of **$261,988,000 plus interest in state civil damages** for losses the states suffered by the state Medicaid programs from the Serono entities' sales and marketing misconduct involving Serostim.

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[2] Assuming payment on December 16, 2005, the federal share of interest will be **$6,947,815.5** ($36,567.45 x 190 days) for a total federal payment of **$312,024,815.50.**

(D) **Serono Labs agreed to be excluded from further participation in all federal health care programs.** The remaining Serono corporate entities agreed to comply with the terms of a sweeping corporate compliance program which, among other things, significantly changes the manner in which the Serono entities conduct the sales and marketing of Serostim, requires independent audits and self-reporting, and requires accurate pricing information to be provided to the United States government.

III. OVERVIEW OF THE CRIMINAL CONDUCT:

A. The Charges:

Count I charges Serono Labs with knowingly and willfully conspiring to violate 21 U.S.C. §§ 331(a) and 333(a)(2) by introducing and delivering for introduction into interstate commerce, with intent to defraud and mislead, adulterated devices. These devices consisted of BIA computer software known as FNA, Cyprus, SomaScan and Cyprus 1.2 Condensed for use in calculating body cell mass and/or diagnosing AIDS wasting based upon BIA resistance and reactance measurements. The devices were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B)(I) because no pre-market approval was obtained from the U.S. Food and Drug Administration ("FDA") to introduce such devices into interstate commerce for these uses.

Title 18 U.S.C. § 371 makes it a crime to knowingly and willfully conspire with another to commit an offense, where thereafter, one of the conspirators commits an overt act in furtherance of the conspiracy. The FDCA provides in pertinent part as follows: Title 21 U.S.C. § 331(a) prohibits introducing into interstate commerce a medical device that is adulterated. Section 351(f)(1)(B) provides that a medical device is adulterated if it has been introduced into

interstate commerce without first obtaining pre-market approval from the FDA. Where an adulterated device is introduced into interstate commerce with intent to defraud or mislead, the misconduct is a felony. 21 U.S.C. § 333(a)(2).

Count II charges Serono Labs with knowingly and willfully conspiring to violate 42 U.S.C. § 1320a-7b(B)(2) by knowingly and willfully offering and paying remuneration in the form of an all expenses paid trip to Cannes, France to physicians to induce them to refer individuals, including Medicaid patients, to pharmacies for the furnishing of the drug Serostim, for which payments were made in whole or in part by the state Medicaid programs.

Title 18 U.S.C. § 371 makes it a crime to knowingly and willfully conspire with another to commit an offense, where thereafter, one of the conspirators commits an overt act in furtherance of the conspiracy. Title 42 U.S.C. § 1320a-7b(b)(2) prohibits the knowing and willful offer or payment of any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce another to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under a federal healthcare program; or to induce another to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made, in whole or in part, under a federal health care program.

The two conspiracies charged in the Information are components of an illegal marketing scheme by the defendant, Serono Labs, and others to increase sales of Serostim, a form of recombinant human growth hormone approved by the FDA for AIDS wasting, a condition characterized by profound, involuntary weight loss in AIDS patients. In August 1996, when

FDA initially granted accelerated approval for Serostim, wasting was an AIDS defining condition and a leading cause of death among those affected by HIV and AIDS.

B. Overview of the Conspiracies:

Shortly following the launch of Serostim in the fall of 1996, the incidence of wasting began to decline markedly as a result of the simultaneous advent of protease inhibitor drugs, administered with other drugs in various "cocktail" combinations commonly referred to as Highly Active Antiretroviral Therapy, or "HAART." The HAART regimens treated the HIV virus itself and, as a result, averted the condition of wasting that Serostim was developed to treat. Consequently, many physicians declined to prescribe Serostim because it was not medically necessary and was expensive (approximately $21,000 for a 12 week course of therapy).

Confronted with a rapidly diminishing market, Serono Labs and others embarked on a campaign to "redefine" AIDS wasting immediately following the launch of Serostim. The company sought to expand the definition of AIDS wasting to encompass newly emerging symptoms exhibited by AIDS patients and promoted Serostim to treat these symptoms, even though the FDA had not evaluated or approved the safety and efficacy of the drug to treat them. Serono Labs's principal marketing tool became bioelectrical impedance analysis, or "BIA," testing, which involved a medical device that the company claimed would "unmask" supposedly "hidden" wasting. In addition to this marketing scheme, Serono Labs and others offered and paid illegal remuneration to physicians in the form of a trip to the AIDS conference in Cannes, France to induce them to prescribe Serostim for their patients.

1. The Conspiracy to Disseminate the Adulterated BIA device

From 1996 through at least 2002, Serono Labs knowingly and willfully conspired with a

medical device manufacturer known as RJL Sciences, Inc., d/b/a RJL Systems, Inc. ("RJL"), and others to develop and disseminate BIAs and accompanying software devices for use in purportedly diagnosing wasting without first obtaining FDA approval for such a diagnostic use.[3] Despite knowing that the devices lacked FDA approval, Serono Labs promoted the use of BIA technology to physicians, patients, state Medicaid agencies and other third-party payors as an appropriate tool for determining whether Serostim should be prescribed and reimbursed. Serono Labs engaged in an array of practices to manipulate the BIA test and to deceive the state Medicaid agencies and others regarding the test's reliability in diagnosing AIDS wasting. The purpose of this conspiracy was to disseminate adulterated BIA devices to obtain millions of dollars in profits to which Serono Labs was not entitled by causing state Medicaid agencies to pay for prescriptions of Serostim that were not medically necessary.

2. The Conspiracy to Offer and Pay Kickbacks to Physicians (Cannes, France)

Serono Labs also knowingly and willfully offered and paid remuneration to physicians and others to induce prescriptions of Serostim for AIDS patients. In the first quarter of 1999, Serono Labs conspired with its employees and others to offer and pay an all-expenses paid trip to a medical conference held in Cannes, France to doctors and their guests (valued between $8,000 and $10,000) in exchange for the doctors writing between 10 to 30 additional prescriptions of

[3] On April 19, 2005, RJL and its President and owner, Rudolph J. Liedtke ("Liedtke"), pled guilty to conspiring with Serono to disseminate these unapproved, and therefore adulterated, BIA software devices. United States v. Rudolph J. Liedtke and RJL Sciences, Inc. d/b/a RJL Systems, Inc., Crim. No. 05-10088-EFH. Sentencing is scheduled for both defendants on February 16, 2006.

Serostim (worth from $210,000 to $630,000).[4] On April 14, 2005, a federal grand jury in Boston, Massachusetts, charged four other individual defendants, all top management in the Serostim business unit, with violating 18 U.S.C. § 371 by knowingly and willfully conspiring to offer and pay remuneration in the form of the Cannes trip to physicians to induce those physicians to prescribe Serostim, in violation of 42 U.S.C. § 1320a-7b(B)(2), and also charged those defendants with substantive kickback charges in violation of 42 U.S.C. § 1320a-7b(B)(2). United States v. John Bruens, Mary Stewart, Melissa Vaughn, and Marc Sirockman, Crim. No. 05-10102-JLT. The case is pending. An interim status conference before the U.S. Magistrate Judge is scheduled on December 19, 2005.

C. Government's Evidence - General Background

The government's evidence relating to Serono Labs criminal conduct consists of, among other things, interviews and grand jury testimony obtained from well over 100 individuals including (1) current and former employees of Serono Labs and related corporate entities, (2) customers of Serono Labs such as physicians, (3) current and former employees of companies with whom Serono Labs engaged in business such as RJL, and (4) employees of various state Medicaid programs and other government agencies. The government's evidence also consists of documentary evidence including, among other records, approximately 1000 boxes of corporate records [over 2 million documents], hundreds of computer disks from employees' computers and computer databases from Serono Labs and the Medicaid programs, bank records, records from

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[4] A former Regional Sales Director, Adam Stupak, pled guilty on December 21, 2004, to three counts of offering kickbacks to New York area physicians in the form of the Cannes trip to induce their prescriptions of Serostim, in violation of 42 U.S.C. § 1320a-7b(B)(2). United States v. Adam Stupak, Crim. No. 04-10367-DPW. Sentencing is scheduled for March 21, 2006.

physicians and other customers of Serono Labs, patient files, and records from companies with whom Serono Labs did business.

1. The Corporate Structure of the Serono Entities

Serono, S.A., formerly known as Ares-Serono, S.A., is an international bio-technology and pharmaceutical company with corporate headquarters located in Geneva, Switzerland. Serono Holding, Inc. was incorporated in 1982 as a wholly owned subsidiary of Serono, S.A. At all relevant times, Serono Holding owned and controlled 100 percent of Serono Laboratories, Inc., a Massachusetts corporation with its principal corporate office located in Massachusetts.

The defendant Serono Labs was incorporated in Massachusetts as a wholly-owned subsidiary of Serono Holding. This corporation holds the assets involved in the fraud described above: all BIA devices and any licenses associated therewith; the BIA software and any copyrights and licenses associated therewith; the RJL contracts and any licenses associated therewith; certain studies conducted by the Serono entities in furtherance of the marketing of Serostim; as well as certain other assets, including contracts the Serono entities entered into with third-parties in connection with the marketing of Serostim; and all assets of Serono Diagnostics, Inc. and Braintree Research Associates. Serono Labs is the corporate entity that has agreed to plead guilty.

The business unit within Serono Labs that was responsible for Serostim sales was initially called Metabolic & Immune Therapy (M&IT). M&IT's sole responsibility was the marketing and sale of Serostim in the United States. In September 2000, following a corporate reorganization, M&IT was merged into a new business unit known as Metabolic Endocrinology North America (MENA), which became responsible for the marketing and sale of Serostim in

both the United States and Canada. Executives in the United States during the relevant time-frame included Mary Stewart, Vice President of Sales, and John Bruens, Vice President of Marketing. Both Stewart and Bruens have been indicted in connection with the Cannes kickback conspiracy.

The sales and marketing of Serostim were carried out through a national sales force, which was, during the relevant time-frame, divided into six sales regions, each of which was led by a Regional Director. The regions included Northeast, New York, Southeast, Central, Mid-Atlantic, and Western. The regional directors supervised sales representatives, known within Serono Labs as clinical consultants. One of those Regional Directors, Adam Stupak (New York region), pled guilty to violations of the Anti-Kickback Act in connection with offers of the Cannes trip to three doctors in exchange for their Serostim prescriptions. Two other regional directors, Marc Sirockman (Northeast region) and Melissa Vaughn (Southeast region) have been indicted for conspiring to violate the Anti-Kickback Act and for substantive kickback charges involving the offer and payment of the Cannes trip to physicians in exchange for Serostim prescriptions. Sirockman, Vaughn, and Stupak reported directly to Stewart.

2. Serostim

Serostim is the proprietary name or trademark of the generic drug, "somatropin." Somatropin is recombinant human growth hormone, consisting generally of growth hormone taken from an animal and modified, using DNA technology, by the addition of the human growth hormone gene. Defendant received accelerated approval from the FDA in August of 1996 for Serostim to treat AIDS wasting, also known as cachexia. Cachexia is a condition involving profound involuntary weight loss in AIDS patients, with a preferential loss of lean body mass

over fat mass. At the time the FDA approved Serostim, AIDS wasting was an AIDS-defining condition that constituted the leading cause of death among AIDS patients.

Serostim was an injectable drug that was prescribed per milligram ("mg.") and was dispensed in vials. The dosing range for Serostim was from 4 to 6 mg. per patient per day based upon the patient's weight. The dose most commonly administered was 6 mg. per day. In August of 1996, the FDA approved Serostim for a 12-week course of treatment, although many patients received Serostim for more than 12 weeks.

Serostim was a very expensive drug. The average wholesale price ("AWP") was $42 per mg. At 6 mg. per day, a prescription for Serostim was 168 mg. per 28-day cycle, and the cost per 28-day cycle was approximately $7056. A twelve-week course of therapy cost approximately $21,168. Due to its cost, among other factors, many physicians treating AIDS patients did not use Serostim as a "first line" or primary choice of therapy.

As mentioned, Serostim came on the market concurrently with the advent of protease inhibitor drugs (HAART drugs). These drugs are often referred to as "AIDS cocktails." Given the decreased viral loads in HIV-positive patients taking these drugs, the incidence and prevalence of the AIDS wasting syndrome began to markedly decline among AIDS patients. Consequently, the demand for Serostim began to drop significantly immediately following launch of the drug in the fall of 1996.

a. Medicaid Reimbursement for Serostim

Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*, established a program to enable the states to furnish medical assistance to certain categories of persons whose income and resources were insufficient to meet the costs of necessary medical services. Commonly called

Medicaid, the program was administered by the states, but was funded jointly by the federal and state governments.

To participate in the Medicaid program, a state was required to develop a plan that was approved by the Secretary of Health and Human Services as meeting federal requirements. The state paid qualified providers for furnishing necessary services covered by the state plan to individuals who were eligible for medical assistance. The federal government contributed a portion of the costs that each participating state incurred in purchasing items and services from qualified providers on behalf of eligible persons. The state bore the remainder of the costs.

State Medicaid programs were "federal health care programs" within the meaning of 18 U.S.C. § 24, in that they were public plans affecting commerce under which medical benefits, items and services were provided to individuals under the plans. The federal government contributed to the costs of prescriptions for persons who were Medicaid beneficiaries, including but not limited to persons disabled due to HIV infection and AIDS under the state Medicaid programs.

Medicaid paid for approximately 80% of all Serostim prescriptions nationwide. The total amount paid by Medicaid for Serostim prescriptions nationwide from 1997 through 2002 was approximately $470 million.

The criminal losses set forth below primarily include losses to the Medicaid programs, and disgorgement of certain profits from non-government programs.

3. The BIA Device and Related Software Devices

The bioelectrical impedance analysis, or BIA, device that was manufactured and sold by Serono Labs's co-conspirators, RJL and Liedtke, consisted of a portable device with two

protruding electrodes to be attached to the hand and foot of human test subjects. The BIA measured the rate at which low levels of electrical current pass through the body. A microchip embedded within the BIA device measured the degree to which the electrical current encountered "impedance" while passing through the body and calculated "resistance" and "reactance" measurements. The resistance and reactance measurements obtained by performing a BIA test on a human subject reflected the degree to which the subject's body resisted the flow of the current and the extent to which the current was stored in the body.

The resistance and reactance measurements generated by the BIA device were used to estimate the body composition of individual humans. Estimates of body composition were computed by applying the resistance and reactance measurements generated by the BIA device to prediction equations. Such prediction equations were developed by mathematically calculating the statistical relationship between the resistance and reactance measurements obtained by performing BIA tests on a sample population of human subjects and actual measurements of body composition for that population. Prediction equations used to estimate body composition of humans varied depending on the characteristics and size of the sample population used to develop the equation and on the methodology used to measure the body composition within that population.

The BIA device was a medical device within the meaning of the FDCA, 21 U.S.C. § 321(h), in that the BIA device was an impedance plethysmograph used to estimate human body composition by estimating "peripheral blood flow by measuring electrical impedance changes in a region of the body such as the arms and legs." 21 C.F.R. § 870.2770.

Each package of computer software used to convert the resistance and reactance

measurements generated by the BIA device into estimates of body composition was a medical device within the meaning of the FDCA in that it was a "component, part, or accessory" to BIA devices pursuant to 21 U.S.C. § 321(h).

D. Relevant Evidence – The Conspiracy to Violate the FDCA Through the Introduction of Adulterated BIA Software Devices Into Interstate Commerce (Count 1)

1. The FDA's Regulation of BIA Devices and Limited Approval of Serostim

The Center for Devices and Radiological Health ("CDRH") was the office within the FDA responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law.

The BIA and computer software devices could not be sold without first obtaining premarket clearance and/or premarket approval from the FDA, depending on the intended use of the devices. FDA could grant what was called a 510(k) premarket clearance if it determined, following review of the data submitted in support of the applicant's premarket notification, that a device was substantially equivalent to a device (known as a "predicate device") that was marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments to the FDCA. A device could only be found substantially equivalent to a predicate device if, among other things, the intended use of the current device was the same as the intended use of a predicate device. If the intended use of the device was different from the intended use of a predicate device, substantial equivalence could not be found. Under such circumstances, the manufacturer could not legally market the device in interstate commerce unless the FDA had first reviewed and approved a premarket application to market the device.

FDA categorized devices into three classes -- Class I, Class II, and Class III -- depending on the degree of regulation necessary to ensure the safety and effectiveness of the devices for their intended uses. Federal law states that devices first introduced into commercial distribution after May 28, 1976, were Class III devices. 21 U.S.C. § 360c(f)(1). A Class III device, unless the subject of a 510(k) premarket clearance, required premarket approval before it could be legally marketed in interstate commerce. 21 U.S.C. § 360e. Premarket approval review by the FDA generally entailed, among other things, a review of clinical trials and scientific data offered to confirm the safety and efficacy of the device as well as a review of the device's labeling, which must include adequate directions for use.

On or about June 24, 1986, RJL and Liedtke submitted a 510(k) premarket notification to FDA's CDRH relating to a BIA device identified therein as "Body Comp Analyzer" and a computer software device accompanying the BIA device. In that 510(k) submission and in ensuing correspondence with CDRH, RJL and Liedtke stated that the Body Comp Analyzer and accompanying computer software had the same intended uses as those identified in a 510(k) premarket notification RJL had filed with CDRH in 1983 - specifically, estimating total body water, lean body mass, and fat - and that the computer software only performed calculations that previously would have been done by hand to estimate body composition. RJL and Liedtke further represented that the prediction equations in the computer software were based on a population consisting of 278 healthy and obese college students whose body composition was measured through hydrostatic weighing. RJL and Liedtke also stated that total body water measurements of the college students were determined using deuterium oxide dilution. RJL and Liedtke represented to CDRH that the intended uses of the BIA device and accompanying

computer software did not include measuring body cell mass or diagnosing any disease state.

Based on the representations made by RJL and Liedtke in their 510(k) submission and related communications, CDRH concluded that the modified Body Comp Analyzer and accompanying computer software were substantially equivalent to a device marketed prior to the medical device amendments of 1976. On February 3, 1987, CDRH granted premarket clearance to RJL to distribute the Body Comp Analyzer and the accompanying computer software devices, referred to by CDRH as the "Modified Model BIA-103 Body Comp Analyzer," for the intended uses of estimating total body water, lean body mass, and fat in healthy humans.

Thereafter, in 1991, the Serono Labs commenced a dialogue with the FDA regarding obtaining an indication for Serostim to treat AIDS wasting, a serious condition of AIDS prior to the advent of the HAART therapy in the mid-1990's. Serono Labs's June, 1991 application with the FDA for designation of Serostim as an orphan drug reflected the small, discrete market the company contemplated for an AIDS wasting drug. In its application, Serono Labs described this disease as one involving a decline in lean body mass, not one involving loss of "body cell mass" ("BCM"). Based on Serono Labs's description of this disease state and data gathered by the Centers for Disease Control (CDC), the FDA granted the company's application for orphan drug protection, designating AIDS wasting as a "rare disease or condition" affecting fewer than 200,000 people in the United States. 21 U.S.C. § 360bb(a)(2).

Following receipt of orphan drug status, Serono Labs began discussions with FDA staff regarding clinical studies for the AIDS wasting indication. During discussions with the medical reviewer at FDA's Center for Drug Evaluation and Research (CDER) regarding the protocols to be followed in conducting the two clinical trials needed to obtain approval for Serostim, Serono

Labs agreed that Serostim's efficacy should be assessed by gains in weight, lean body mass (not BCM), and physical performance in patients who had experienced severe weight loss.

Serono Labs submitted a new drug application (NDA) for Serostim in the Fall of 1995. In reviewing the clinical trials results, FDA concluded that only one of two studies demonstrated that Serostim was effective in AIDS wasting. Because the results of the first study were not corroborated by the second, and in light of the numerous adverse side-effects experienced by patients in both studies, FDA's medical reviewer recommended against approval of the drug.

Despite the marginal efficacy demonstrated in the clinical trials for Serostim, FDA continued to evaluate Serono Labs's NDA for an AIDS wasting indication because the disease was so serious. An Advisory Committee, consisting of experts in the fields of endocrinology, metabolism and AIDS, was convened in the Spring of 1996, and public hearings were held. Notwithstanding very moving testimony by AIDS patients who stated that Serostim had helped them, the committee voted 8 to 7 to deny approval of the drug.

Nevertheless, the Advisory Committee raised the possibility of granting accelerated approval for Serostim under subpart H of 21 C.F.R. § 314. In 1992, FDA promulgated regulations designed to make new drugs that treat serious or life-threatening illnesses available to patients more quickly. Under these regulations, the FDA may grant such approval where clinical trials show that the drug has an effect on a "surrogate endpoint that is reasonably likely . . . to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity." 21 C.F.R. § 314.510. Following further consideration, the FDA granted accelerated approval to Serostim in light of the pressing need to make the drug available to AIDS patients suffering from wasting syndrome.

The FDA label for Serostim incorporated the findings of the studies Serono Labs performed and specified the approved indication. The "clinical pharmacology" section of the product label described the disease state as follows:

> AIDS-associated wasting is a metabolic disorder characterized by abnormalities of intermediary metabolism resulting in weight loss, inappropriate depletion of lean body mass (LBM), and paradoxical preservation of body fat. LBM includes primarily skeletal muscle, organ tissue, blood and blood constituents, and both intracellular and extracellular water. Depletion of LBM results in muscle weakness, organ failure, and death. Unlike nutritional intervention for AIDS-associated wasting, in which supplemental calories are converted predominantly to body fat, Serostim™ treatment resulted in an increase in LBM and a decrease in body fat with a significant increase in body weight due to the dominant effect of LBM gain.

The label further described the studies Serono Labs had performed on the drug and made it clear that the trial showing Serostim to be effective had been performed on patients with "AIDS wasting" who had "unintentional weight loss of at least 10% or weighed less than 90% of the lower limit of ideal body weight."

After receiving accelerated approval for Serostim, Serono Labs submitted a proposed protocol to FDA governing the conduct of the required Phase IV confirmatory trial. Serono Labs raised the possibility of testing Serostim on patients who had unintentionally lost less than 10 percent of the body weight. Serono Labs stated that it sought this change because the company was experiencing difficulty recruiting patients who met the 10 percent weight loss threshold. Serono Labs was having difficulty recruiting patients because the incidence of AIDs wasting was declining due to the availability of the HAART therapy. In tracking the AIDS epidemic, the Centers for Disease Control (CDC) had characterized AIDS wasting as involving loss of 10% or more of body weight. The FDA objected to Serono Labs's request that the confirmatory study

lower the 10% weight loss figure as the benchmark of AIDS wasting; in response, Serono Labs agreed to continue to use the 10% weight loss criterion. Serono Labs also raised with FDA the possibility of measuring changes in "body cell mass," or "BCM," instead of "lean body mass," or "LBM," in the study. Following objections by FDA to measuring changes in BCM rather than LBM during the Phase IV confirmatory trial, Serono Labs dropped the proposal to measure BCM and agreed to continue to measure changes in LBM in the confirmatory trial.

As a result of its detailed discussions with the FDA, Serono Labs knew and understood that the disease AIDS wasting for which Serostim had been tested and approved by FDA consisted of profound, involuntary weight loss of 10% or more of body weight, characterized by a loss of LBM. Serono Labs further knew and understood that FDA had not accepted any definition of AIDS wasting as involving the purported loss of BCM in the testing and approval of Serostim.

2. The Conspiracy to Introduce Adulterated BIA Machines and Computer Software in Interstate Commerce

Beginning as early as September 1996, and continuing thereafter through at least January 2002, Serono Labs launched a campaign to "redefine AIDS wasting" in order to create a market for Serostim by expanding the disease state for which Serostim could be prescribed as a treatment. The sales force made sales presentations and disseminated literature stating that wasting was being "masked" by weight gain in the post-HAART era and that patients were still experiencing AIDS wasting following the advent of HAART, despite an absence of weight loss. The company trained its sales and marketing employees to represent to physicians, patients, and others that BCM was the most metabolically active component of the body and that patients who had lost BCM were wasting, even if they had lost no weight or had actually gained weight. The

company taught its sales representatives to advocate to physicians that estimates of BCM in humans could be made by using BIA machines with certain software devices that purported to compute estimates of BCM. To "unmask" AIDS wasting, the company promoted the use of adulterated BIA and accompanying computer software devices to measure BCM. The purpose of the conspiracy to introduce the adulterated devices into interstate commerce was to obtain millions of dollars in sales of Serostim by generating prescriptions for AIDS patients who did not need the drug because they were not actually wasting.

3. The Adulterated BIA Machines and Computer Software

Serono Labs purchased BIA and software devices from RJL its President and owner, Liedtke. RJL and Liedtke developed, manufactured and sold BIA and computer software devices, including various software packages known as FNA, SomaScan, and Cyprus 1.2 Condensed, in conjunction with, and pursuant to agreements with Serono Labs and others. Serono Labs, RJL and others developed various versions of software for the BIA device that were designed to calculate, among other things, BCM, total body water, fat free mass, and intracellular and extracellular water. The various software packages were named "Fluid and Nutrition Analysis" or "FNA." "Cyprus," "SomaScan," and "Cyprus 1.2 Condensed." Each of these software packages, pursuant to 21 U.S.C. § 351(f)(1)(B)(I), required FDA approval before they could be legally marketed for use in measuring BCM and/or diagnosing AIDS wasting based upon BIA resistance and reactance measurements as these were new intended uses of the BIA. At no time did any individual or entity submit an application for premarket approval to the FDA with respect to any of these software packages, nor has FDA ever approved an application for premarket approval for any of the software packages under 21 U.S.C. § 360e.

a. The FNA Software

In 1994, RJL and Liedtke assisted others in developing a prediction equation that would purportedly calculate estimates of BCM using the BIA resistance and reactance readings. This prediction equation (referred to in the Information as the "Z equation") purported to estimate BCM based upon measurements of total body potassium in a population referred to in the Information as the "ABC database" that consisted of approximately 332 humans, including individuals who were healthy and others who had been tested as HIV-positive.

Also in 1994, RJL, Liedtke, and others developed new computer software for use in interpreting BIA test results that incorporated the Z equation and marketed the software under the name "Fluid and Nutrition Analysis," or "FNA." The FNA software purported to calculate the individual test subject's estimated BCM, total body water, intracellular and extracellular water, fat free mass, extracellular tissue, and fat. The FNA software also computed purported "normal" ranges for the individual test subject's total body water and intracellular and extracellular water by comparing the individual's BIA test results to a select portion of the population included in the ABC database. The inclusion of the Z equation and the ABC database in the FNA software, and the use of the computer software to purportedly measure BCM and as a tool for diagnosing AIDS wasting, were new intended uses that required premarket approval from FDA before their introduction or delivery for introduction into interstate commerce. No such approval was sought or obtained. Between September, 1995, and June, 1996, RJL shipped approximately 25 BIA devices together with FNA Version 3.1 software packages to Serono Labs for use in evaluating body composition in AIDS patients.

b. The Cyprus Software

The "Cyprus" software, developed for the BIA device commencing in or about 1998, incorporated the Z equation for estimating BCM and calculated purported measurements of BCM, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus software further computed purported normal ranges for each of these measurements for individual test subjects by comparing the individual's test results to a select portion of a database of humans derived from the National Health and Nutrition Examination Survey (NHANES). This new software required premarket approval from FDA before introduction or delivery for introduction into interstate commerce. No such approval was sought or obtained.

c. The SomaScan Software

The "SomaScan" software, developed for the BIA device commencing in or about August, 1999, incorporated the Z equation for estimating BCM and calculated purported measurements of BCM, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The SomaScan software further computed purported precise "ideal" amounts for each of these measurements for individual test subjects by comparing the individual's test results to a select portion of the NHANES database and eliminating any standard deviation from the calculations. The SomaScan software was not submitted to FDA for premarket approval and was not approved by FDA for shipment in interstate commerce for the intended uses of measuring BCM or diagnosing AIDS wasting. The inclusion of the Z equation, employing the NHANES database as the population base for computing "ideal" body composition values in the SomaScan software, and the use of the computer software to measure

BCM and as a tool for diagnosing AIDS wasting were new intended uses, and required premarket approval from FDA before introduction or delivery for introduction into interstate commerce. No such approval was sought or obtained.

d. The Cyprus 1.2 Condensed Software

The "Cyprus 1.2 Condensed" software, developed for the BIA device in or about February, 2000, incorporated the Z equation for estimating body cell mass and calculated purported measurements of BCM, fat, extracellular mass, fat free mass, intracellular and extracellular water, and total body water. The Cyprus 1.2 Condensed software also computed purported "normal" amounts and "normal" ranges for these values for each individual by comparing the individual test subject's results to a select portion of the NHANES database and including a standard deviation for these calculations. The inclusion of the Z equation, employing the NHANES database as the population base for computing "normal" body composition values in the software, and the use of the computer software to measure BCM and as a tool for diagnosing AIDS wasting, were new intended uses, and required premarket approval from FDA before introduction or delivery for introduction into interstate commerce. No such approval was sought or obtained.

2. The Use of the Adulterated BIA Machines and Computer Software

By 1997, Serono Labs launched a campaign to redefine AIDS wasting to include patients who had lost no weight at all, but instead had experienced a loss of BCM, which they maintained was the "metabolically active" component of lean body mass (LBM). Serono Labs claimed that "BCM wasting" was a condition that could be diagnosed using BIA devices. Despite the fact that "BCM wasting" was not the measure of wasting recognized by the CDC, or used by Serono

Labs and FDA during the clinical trials, Serono Labs aggressively sought to "educate" practitioners regarding the virtues of using Serostim to treat this "new face of wasting." According to the sale pitches Serono Labs sales representatives made to doctors, patients, and the AIDS community generally, wasting patients no longer exhibited the "concentration camp survivor" look. Rather, Serono Labs recast wasting syndrome as a "metabolic derangement" that was being "masked" by HAART therapy. Consequently, Serono Labs claimed it was not possible to tell whether patients were wasting simply by looking at them. According to Serono Labs, even if patients were not losing weight - and had actually *gained* weight - there could be no certainty that they were free from the wasting syndrome. According to Serono Labs, given current technology, BCM could *only* be measured by performing BIA tests in tandem with certain software. Serono Labs's central marketing tool became the BIA test.

Serono Labs used the BIA device to "expand" the market beyond the patient population Serostim had received accelerated approval to treat through fraud, deceit, and affirmative misrepresentations. Serono Labs trained its clinical consultants (sales representatives) to perform the test, required them to perform it themselves directly on patients, and instructed them on how to interpret the test for doctors and patients. The company's sales force aggressively sought out opportunities to market Serostim directly to AIDS patients by performing BIA tests on them whenever possible. Clinical consultants were required to report - and were even rated on - their "BIA hit rate," *i.e.*, the number of BIAs performed that resulted in Serostim prescriptions. To meet sales goals, clinical consultants devised methods of manipulating the test results by changing the patient's height, weight, and the numerical "resistance" and "reactance" readings generated by the BIA itself, so that the test showed patients to be wasting who, in fact,

were not. Serono Labs also marketed the BIA tests to state Medicaid agencies and convinced several, including California and Florida, who had the highest number of AIDS patients, to adopt this test as a reimbursement measure.

Serono Labs also launched an extensive campaign to promote the concept of "unmasking" AIDS wasting. The company disseminated to medical professionals and patients such gifts as African masks and coffee mugs bearing masked faces that "unmasked" when filled with hot liquid. One regional sales director urged her sales force to say that the patients could be "rotting inside," likening the inability to readily detect wasting in the post-HAART era to the difficulty of distinguishing between a low-fat and regular-fat muffin. Gifts bearing the Serostim label and the admonition "there is no time to waste" underscored the sense of urgency Serono Labs endeavored to convey regarding the need to "unmask" and treat wasting with Serostim. The company launched a website in 1998 with the URL www.aidswasting.com entitled "AIDS Wasting is Being Masked: Unmask the Issue" aimed at educating the patient population about the continuing threat presented by wasting syndrome.

Serono Labs and others disseminated adulterated BIA devices and computer software to promote the diagnosis of AIDS wasting as a disease state involving the loss of BCM, and to compute "ideal" or "normal" levels of BCM and other body composition parameters, without first obtaining FDA approval. Serono Labs and others caused physicians to prescribe and third party payors to pay for Serostim based on misrepresentations and omissions of material facts regarding the validity of BIA testing in diagnosing AIDS wasting and did not disclose that the BIA software devices had not been approved by FDA or scientifically validated for the purposes of determining whether patients were experiencing purported changes in BCM and/or suffering

from AIDS wasting. In some cases, Serono Labs sales representatives actually manipulated the BIA test results for individual patients to support prescriptions under the false and fraudulent criteria that the company was promoting. In other cases, the tests were given on patients who had not properly fasted prior to administration of the test, rendering the results meaningless; nevertheless, Serono Labs advocated using these test results as the bases for prescriptions. In sum, Serono Labs caused third-party payors, including Medicaid, to reimburse for Serostim prescriptions that would not have been written and/or for which the third-party payors would not have paid. The evidence indicates that of all the prescriptions written, approximately 85% of those were unnecessary for the patients for whom they were prescribed.

Serono Labs and its co-conspirators engaged in numerous overt acts to introduce and deliver for introduction into interstate commerce, with the intent to defraud and mislead, adulterated medical devices consisting of BIA computer software for use in calculating body cell mass and/or diagnosing AIDs wasting based upon BIA resistance and reactance measurements, because no premarket approval had been obtained from the FDA to introduce those medical devices into interstate commerce for that purpose.

E. Relevant Evidence – The Cannes Kickback Conspiracy (Count II)

During early March of 1999, Serono Labs through its employees in their M&IT unit, offered physicians an all expenses paid trip to the 3rd International Conference on Nutrition and HIV Infection held in Cannes, France ("the Cannes Conference") from April 22-25, 1999, in return for the doctors writing up to 30 prescriptions of Serostim. Serono Labs knew that the offers were illegal. In fact, some physicians rebuffed Serono Labs and expressly complained about the offered bribe. In total, the marketing department of Serono Labs sent 13 physicians to

Cannes.

In February of 1999, the first fiscal quarter of 1999, M&IT was falling short of its sales forecasts and had only met approximately 80% of their goal by the end of February. A top officer of the Serono entities was coming to the United States to meet with each of the U.S. business units in early March, 1999, as well as to attend the National Sales Meeting to take place in Massachusetts from March 15-19, 1999. M&IT therefore needed to produce. In mid-February, each of the regional directors was instructed to provide a business plan to make the sales numbers for the rest of the quarter.

On March 1, 1999, an emergency meeting of the M&IT top management, including the regional directors, was called at the Boston Harbor Hotel in Boston, Massachusetts. John Bruens (VP of Marketing) and Mary Stewart (VP of Sales) led the meeting. The meeting went late into the night. The regional directors were told they needed to "dig their way out" of this fiscal crisis and were informed of a "$6m-6 Day Plan." Bruens instructed the regional directors that the company would send key doctors to the Cannes Conference in April, 1999, in return for writing 30 scripts of Serostim. The Regional Directors were required to identify key doctors who were "high potential AIDS treaters who were also Serostim fans and ask them to put 30 patients on, and then if they did that. . . in a week . . . they would get to go to Cannes for an AIDS nutritional conference." This offer was a straightforward kickback -- physicians would receive a trip to the Cannes conference in return for putting 30 patients on Serostim. Among other topics to be discussed at the conference were lipodystrophy and immune reconstitution, two off-label uses for Serostim. Although the precise number of prescriptions per physician changed over time, the original plan, as originally explained by Bruens and Stewart at the Boston Harbor Hotel, was to

increase sales by $6 million in six days.

Stewart and Bruens told the Regional Directors to target their top prescribers to get them to write scripts. Stewart coined the term the "$6m-6 Day Plan" in her follow-up e-mail. In that e-mail, Stewart spelled out exactly what Regional Directors were to do, including instructing them what they were to tell their clinical consultants to do, *i.e.*, identifying which doctors they were to target, requiring that the clinical consultants report their results (new scripts) daily, and zeroing in on doctors who could give Serono Labs results -- meaning new prescriptions. Stewart also instructed another employee of Serono Labs to create a special spread sheet for this reporting, which was used by the Regional Directors to report daily results until March 11, 1999. Stewart reminded everyone that this was to be a "team effort" so that they could "deliver [their] numbers," meaning sales.

The Regional Directors were expected to make the Cannes offers in early March of 1999 so that they could get the necessary prescriptions to increase sales. Approximately twenty (20) doctors were offered the trip and 13 accepted. Several doctors denied a connection between the trip and an increase in prescriptions; several were upset by the proposition and so advised the sales representatives; some indicated acquiescence to the proposition but did not go; others agreed to go but did not go; still others agreed to go and did go. The Regional Directors and others telephoned and e-mailed the sales force passing forward the directions of the top management, including Bruens and Stewart, advising of the plan, and implementing the plan. John Bruens directed the plan; therefore his executive assistant was the contact person for the doctors and was responsible for issuing invitations to the doctors, coordinating travel, itineraries, and organizing the dinners at Cannes sponsored by Serono Labs.

After the March 1st meeting in Boston, the Regional Directors implemented the program. Expense reports confirm meetings during the next few days with clinical consultants and doctors. One regional director reached out to his clinical consultants who assisted him in calling upon the "top prescribers" that he was targeting. Late in the evening of March 1, 1999, one physician received a voice mail from a Regional Director advising him that the company was targeting their top prescribers and would offer them a trip to the Cannes conference in return for their writing 30 scripts within 30 days. At least two doctors called the offer an "inducement," "inappropriate" and "wrong." Certain doctors were upset about the offer and refused to participate.

The offers for the doctors to attend the Cannes conference were the fuel to make the "$6 million in 6 days" sales plan a success. At the National Sales Meeting in March, John Bruens announced that "marketing" had invited 10 doctors to the Cannes Conference from states including New York, New Jersey, Florida, California, and Pennsylvania. Each of these states had state Medicaid programs with substantial reimbursements for Serostim. The Bruens PowerPoint stated that "[e]ach invitee has committed to conducting two regional speaking programs to summarize the meeting proceedings." The speaking programs were not part of the original offer to the doctors. If the doctors did speak after the conference, they were independently compensated by Serono Labs for those talks. The program was at least partially successful in generating increased prescriptions of Serostim during that fiscal quarter and beyond.

IV. Serono's Civil Liability

In the course of the investigation, the government uncovered various other conduct by

Serono Labs and its related companies that was improper. However, at this time the government's evidence in those additional areas does not establish criminal scienter. Accordingly, the losses from this conduct were not included as relevant conduct in the calculation of the criminal fine. However, the evidence was sufficient to establish violations of various civil statutes, including the civil False Claims Act, 31 U.S.C. § 1329 *et seq.* and other federal civil law.[5] The civil violations alleged included certain additional kickback issues and off-label marketing Serostim for lipodystrophy. The company agreed to pay double the loss amounts in the civil settlement agreement for the conduct set forth below. The government assessed Serono's willingness to make the government whole and pay additional damages in reaching its conclusion that the global resolution was fair and appropriate, and also in reaching the decision that any Serono corporate entity should be permitted to continue to do business with the federal health care programs, even under a strict corporate integrity agreement with the Inspector General's Office of the Department of Health and Human Services.

A. Free BIA program

During the Winter and Spring of 1997, Serono Labs gave doctors BIAs through the "Serono BIA Program." At first, doctors could purchase or lease the machines or accept a BIA in lieu of the grant fee Serono Labs paid the physicians for patients enrolled in an observational "study" known as "SeronAIDS" (under which Serono Labs paid them $75 per patient per quarter to report their responses to the drug) until the value of the machine was "paid off." The doctors were offered a BIA in return for placing 10 patients on Serostim and enrolling them in the

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[5] As part of the civil settlement agreement, the Company did not admit liability for the conduct described in this section.

SeronAIDs observational study. The machines were worth about $4,000. The difficulty in proving criminal intent with the BIA program is that physicians are often paid for participation in surveys and studies; and while the BIA machines were probably worth more than the fair market value of the physician's time, the evidence of intent did not show willfulness.

B. Pharmacy Payments

During this time frame, Serono Labs also offered rebates to pharmacies to dispense Serostim. From 1997-1999, Serono Labs was receiving dispensing data from national pharmacy data collection companies such as NDC and Source. At the same time, Serono Labs entered into "Data Collection Agreements" with certain high-volume HIV specialty pharmacies under which Serono Labs paid these pharmacies $2 per mg for all Serostim dispensed, ostensibly for reporting data concerning the drug dispensed. This amount was in addition to the significant profit that these pharmacies were already making on the sale of the drug. In 2000, the $2 per mg. pharmacy contracts were cancelled and replaced by new "Preferred Provider" contracts that paid a .375% chargeback to the pharmacies of approximately $1.30 per mg rebate. The Data Collection and Preferred Provider agreements set off competition in the market between pharmacies to obtain these rebates. The payments made by virtue of these contracts could be substantial to a pharmacy; however, both data fees and chargebacks were common practices within the industry. As with the BIA give-away, the evidence of willfulness in connection with the pharmacy payments was insufficient to establish criminal culpability.

C. SeronAIDs/SALSA

SeronAIDS was an "observational study," sometimes confused with the Phase IV confirmatory study required by FDA. Doctors were paid $75 per patient per quarter to collect

and provide certain data (on a one page form) about their patients to Serono Labs. This study was ostensibly to be used to examine the efficacy, dosage, and side effects of Serostim. Patients had to be using Serostim in order to be a part of this study. The data collected was not ultimately used in any study, nor did Serono Labs give the physicians any feedback from the data they submitted. The doctors were considered "thought leaders" by Serono Labs, and were some of the physicians who prescribed the most Serostim for their patients. In 1998 and 1999, the company added a new component to this program, called the Self-Ascertained Lipodystrophy Self-Assessment Survey, known as SALSA. Serono Labs enlisted physicians in a supposed "observational study," or "cohort." purportedly designed to gather information about the nature and prevalence of lipodystrophy symptoms in the patient population. This "survey" consisted of a questionnaire completed by doctors and patients that provided medical information about the patients and the patients' own perceptions of changes in their body shape. Physicians were paid $200 for each patient they signed up and $75 for each SALSA form they returned to the company. Serono Labs's sales representatives used the questionnaire as an opportunity to discuss lipodystrophy with physicians and patients and to raise their awareness about the possibility of treating lipodystrophy with growth hormone. SeronAIDS and SALSA were ostensibly studies or surveys, but whether the payments constituted fair market value for the physicians' time is hard to definitively assess. Thus, again, the evidence was not sufficient to establish criminal intent.

D. Off-Label Marketing of Serostim for Lipodystrophy

Serono Labs also sought to increase the sales of Serostim by marketing it to AIDS patients with lipodystrophy, a metabolic illness associated with the use of highly active

antiretroviral drugs and characterized by the maldistribution of fat in various parts of the body. Serono Labs marketed Serostim for the off-label use of lipodystrophy by, among other things, paying doctors, nutritionists and others to give speeches and author papers about the use of Serostim in that setting and sponsoring studies for the use of th drug in that indication. Serono sought to be a leader in lipodystrophy research and to establish that Serostim as the drug of choice to correct the "underlying deranged metabolism associated with lipodystrophy." Serono Labs proactively educated the medical community and third-party payors that Serostim is medically necessary treatment for both lipodystrophy. The company argued that lipodystrophy often masks BCM wasting, that BIA testing could be used to uncover this problem, and that Serostim was medically appropriate and safe for patients with dual diagnoses of lipodystrophy and BCM. In addition, Serono Labs argued that lipoatrophy, a form of lipodystrophy involving the depletion of fat, was a form of AIDS wasting and marketed Serostim for patients experiencing lipoatrophy. The company promoted Medicaid reimbursement for lipodystrophy by mischaracterizing this disease as a form of AIDS wasting, and encouraged patient diagnoses such as "peripheral wasting" or "wasting complicated by lipodystrophy" in order to get Medicaid to pay for Serostim claims. Medicaid paid for prescriptions of Serostim for many of these lipodystrophy patients. While this marketing was for an unapproved indication, it involved the use of studies and speeches by physicians who spoke about the use of the drug to other physicians. The evidence collected at this time in the investigation is insufficient to establish that the conduct was undertaken with an intent to defraud or mislead, and thus it is not included in the criminal calculations, but it is being resolved civilly.

V. CRIMINAL AND CIVIL LOSS CALCULATIONS

The total Medicaid reimbursement for Serostim from 1997 through 2004, net of rebates, was $524,192,000. Six states were the primary payors for this drug: California, Florida, Illinois, Missouri, New Jersey, and New York. These states paid for approximately 90% of the Medicaid sales. After accounting for approximately 3.02% of sales caused by fraud not attributable to Serono Labs and its related entites, the net total payments by Medicaid was **$518,276,000**. In fact, many of these state Medicaid programs suffered cost-cutting measures during these years from the burden created by payments for Serostim. While some of the Serostim was undoubtedly needed for AIDs patients during this period, as a result of this global resolution, each of these state Medicaid programs will receive all of the Serostim for which they paid during the relevant period for free.

A spreadsheet setting forth both the criminal and civil loss calculations, and relevant criminal fine multiplier, civil multipliers, and total damages that are included in this global resolution has been submitted to the Court and is included as an exhibit to the Presentence Report. Although not attached as an exhibit hereto, it is incorporated herein by reference for the Court's convenience. The parties have reached an agreed upon loss figure, as set forth in the plea agreement, and referenced herein. It was calculated as follows:

A. Criminal Losses (and associated civil recoveries) for Count I - introduction of adulterated BIA devices and computer software into interstate commerce with intent to defraud or mislead

To determine the loss for introduction of adulterated BIA devices and computer software into interstate commerce, we applied Serono Labs's internal analyses (made by its marketing analysts during the regular course of business) of the annual percentages of its sales attributable

to BCM wasting to the Medicaid and other federal program reimbursements for Serostim. From these analyses, we estimated that, for the 1998 to 2004 time period, the loss to the Medicaid program was $86.9 million for introduction of adulterated BIA devices and computer software into interstate commerce. The detailed state by state losses are set forth in Spreadsheet B.

In addition to Medicaid program damages for the adulterated BIA devices, we analyzed the gain or profit to Serono Labs from the illegal conduct for private side payors as well. We looked at the sales figure for each year from 1998 to 2002, used the gross margin as reflected in the company's internal financial documents, applied the percentage attributable to BCM from Serono's internal marketing documents, and calculated the ill-gotten gains from private side conduct in an amount of $18,104,000, as reflected in Spreadsheet D.

Thus, the total single loss figure or base fine amount for Count I is agreed at $104,914,000. As set forth in the plea agreement, Serono Labs has agreed that the criminal fine multiplier is calculated at 1.2 times[6] the single loss, for a criminal fine of $125,896,800 associated with Count I.

In addition to the criminal fine, based upon that same loss figure of $86.9 million, the Serono entities have agreed to pay another 3.0 times the single loss figure as civil damages under the civil False Claims Act in connection with this conduct, or $260,699,000, which includes restitution that will be returned directly to each of the federal and state programs, to make those programs whole. Thus, a restitution order is not needed in connection with Count I. The total agreed upon recovery in connection the introduction of these adulterated devices is thus 4.2 times the single loss figure.

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[6] The plea agreement sets forth the details of the parties' concurrence as to the proper determination of the 1.2 multiplier.

B. Criminal losses (and associated civil recoveries) for Count II -- the Cannes Kickback Conspiracy

To calculate loss from the Cannes kickbacks, the total amount of Medicaid payments for Serostim prescriptions written by the physicians who received the trip was estimated based upon the assumption that the physician actually wrote the total number of Serostim prescriptions required in that program. The single loss was thus $9,200,000. Serono Labs agrees with this loss figure, and the application of the 1.2 multiplier yields a criminal fine of $11,040,000 in connection with the misconduct in Count II. In addition, Serono agreed to pay an additional 3.0 times that loss figure as part of civil damages, or another $27,600,000, which will include complete restitution to be returned directly to each of the federal and state programs to make those programs whole. Thus, a separate restitution order is not needed for Count II. As with the loss in Count I, the total agreed upon recovery in connection with the Cannes kickback conspiracy, civil and criminal, is 4.2 times the single loss figure.

C. Civil Damages for Additional Non-Criminal Conduct

For off-label marketing of lipodystrophy, the same approach was used as for calculating the losses from introduction of the adulterated BIA devices. Thus, damages from the off label marketing of Serostim for lipodystrophy were estimated at $128,485,000. That amount was then discounted because a certain percentage of the sales of Serostim for lipodystrophy were due to factors other than the company's off-label marketing. Such factors include, for example, physicians' independent knowledge of the use of Serostim for lipodystrophy. Based on these other causation factors, we estimated the loss from off-label marketing to $92,370,000. Serono has agreed to pay double damages civilly, or $184,741,000 to resolve this misconduct.

For the civil kickback analysis, the total amount of Medicaid payments for Serostim

prescriptions written by physicians who received kickbacks was estimated. That estimate was based upon an assumption that the physician actually wrote the total number of Serostim prescriptions required in exchange for the particular kickback at issue. Using this methodology, damages were estimated at $10.4M in damages for the BIA give-away and $12.6M for the survey payments. Serono agreed to pay double damages for this conduct civilly.

Similarly, the total amount of Medicaid payments for Serostim prescriptions filled by pharmacies which received kickbacks was estimated, including the rebates and the discounts. From this total, we deducted monies already recovered as damages caused by the off-label and adulteration violations and physician kickback violations. Based on this methodology, single damages of $48.025 million were calculated for pharmacy kickbacks. All of that loss is being recovered as part of the civil resolution.

D. Complication of Non-Government Payors

Although the ill-gotten gain from both government and non-government payors is included as the basis for the criminal base fine (based upon a calculation of ill-gotten gains for the non-government portion), to determine which non-governmental payors might have suffered losses for purposes of fashioning a restitution order will unduly complicate and prolong the sentencing process. As in the case involving TAP Pharmaceutical Products, Inc., the government has no way of determining in any reasonable period of time which of the over 800 private insurance payors and programs and more than 9000 patients may have paid for a prescription of Serostim based on BIA results for loss of BCM as basis for an AIDS wasting diagnosis, or for calculating how much the each may have lost. To calculate and negotiate the resolution for only the Medicaid program took over a year. To identify the patients, trace back

to the payors, determine the individual payor's rules for reimbursement and whether the claim was paid, and ultimately determine what amount of loss might have been suffered for purposes of fashioning a restitution order would unduly complicate and prolong the sentencing process to a degree that the need to provide restitution to all victims is outweighed by the burden on the sentencing process, especially where, as here, over 80% of the losses suffered in this case were sustained by the Medicaid program (jointly funded by both the federal and state governments), and which will be fully recompensed from the amounts paid as part of the civil settlement agreement. See, 18 U.S.C. § 3553A(c)(3)(B). Thus, the United States agrees not to seek a separate restitution order as part of the resolution of the Information and the parties agree that the disposition of the case does not include a restitution order.

VI. CONCLUSION

Wherefore, for all the foregoing reasons, the United States requests that the Court accept the plea of guilty of the defendant, Serono Laboratories, Inc., and impose sentence in accordance with the parties' Plea Agreement.

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CERTIFICATE OF SERVICE

I hereby certify that on a true copy of the above document was served upon the attorney of record for each other party by hand delivery and electronic mail on December 14, 2005.

/s/ Mary Elizabeth Carmody
_____
MARY ELIZABETH CARMODY
Assistant U.S. Attorney